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10/533,514

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Linzhao Cheng

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DLA PIPER US LLP
4365 EXECUTIVE DRIVE
SUITE 1100
SAN DIEGO, CA 92121-2133

EXAMINER

CROUCH, DEBORAH

ART UNIT

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1632

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--|---------------------------------------|--|
| Office Action Summary | Application No. 10/533,514 | Applicant(s) CHENG, LINZHAO | |
| | Examiner Deborah Crouch, Ph.D. | Art Unit 1632 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) 34-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 and 52-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/11/08</u> . | 6) <input type="checkbox"/> Other: _____ |

Applicant's election of group I, claims 1-33 and 52-56 in the reply filed on June 2, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 34-51 have been withdrawn from consideration as to a non-elected invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 55 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 55 is to "a culture" and depends from claim 52. Claim 52 is to a "method for obtaining." Therefore claim 55 is confusing as it does not properly limit or depend from claim 52.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

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only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bongso et al. (1994) Human Reproduction, Vol. 9, pages 2110-2117.

Bongso teaches isolated hES cells (page 2112, col. 1, parag. 1). All hES cells required, as an inherent property, either a feeder cell layer or feeder cell conditioned media. The claims do not require the presence of the feeder cells, only that the hES cells depend on them for growth. In a side by side comparison, a patentable distinction could not be discerned between the claimed hES cells and those of Bongso. Thus, Bongso anticipates the claimed invention. In the alternative, as the hES cells of the claims and those of Bongso are not patentably distinct, any differences are obvious differences.

Claims 10-14, 17-19, 22-25 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Bongso et al. (1994) Human Reproduction, Vol. 9, pages 2110-2117.

Bongso teaches a culture of hES cells and human fallopian tube epithelial cells, where the epithelial cells were isolated from adult women (page 2111, col. 1, parag. 2, lines 1-6). As the feeder cells are a culture, some of the epithelial cells will be undergoing senescence and be non-supportive. Bongso further teaches hES cell growth

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and expansion (). The hES cells of Bongso are seen as isolated from their in vivo environment. Further, hES cells inherently express SSEA-4, Oct-4, alkaline phosphatase and do not express SSEA-1. Bongso in teaching methods for obtaining hES cells, those cells would meet the characteristics of hES cells. Thus, Bongso clearly anticipates the claimed invention.

Claims 10, 16, 17, 21, 26-28, 52-54 and 56 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Xu et al., Nature Biotech, October 2001, pages 971-974.

Xu teaches a culture of hES cells grown in media supplemented with conditioned media prepared from TERT immortalized human foreskin fibroblasts (page 971, col. 2, parag. 1, lines 2-11). Xu teaches a method of subculturing by indication of passage 32 (page 972, Figure 1). Xu further teaches a method of obtaining hES cells comprising culturing hES cells in BJ5ta conditioned media ().hES cells inherently express SSEA-4, Oct-4, alkaline phosphatase and do not express SSEA-1. Thus, Xu clearly anticipates the claimed invention.

Claims 31-33 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Thomson et al. (1998) Science, Vol. 282, 06 November 1998, pages 1145-1147.

Thomson teaches the cryopreservation of hES cells from each cell line, meaning at least one frozen aliquot and a plurality of frozen aliquots are taught (page 1145, col. 2, parag. 1, lines 17-21). While the method of culturing hES cells of the claims is distinct from Thomson, it is not clear that the frozen hES cells would be. Thus, Thomson clearly anticipates the claimed invention.

Claims 17 and 21 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by PGPub 20050037488 (Mitalipov).

Mitalipov teaches the growth of hES cells on human bone marrow stromal cells (parag. [0050] and [0051]). The BMSC's act as feeder cells. Thus Mitalipov clearly anticipates the claimed invention.

Claims 17, 26, 27, 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xu et al., Nature Biotech, October 2001, pages 971-974 in view of U.S. Patent 6,921,632 issued July 26, 2005 (Lim).

Xu teaches a culture of hES cells grown in media supplemented with conditioned media prepared from TERT immortalized human foreskin fibroblasts (page 971, col. 2, parag. 1, lines 2-11). Xu teaches a method of subculturing by indication of passage 32 (page 972, Figure 1).

Lim teaches the cryopreservation of hES cells in media and a cryopreservative such that the hES cells remain viable upon thawing (col. 16, lines 44-61). Lim also teaches subculture of hES cells (col. 14, lines 60-67). While Lim does not teach freezing hES cells prior to subculture, it was well known and practiced within the art at the time of filing, to freeze cell samples throughout their establishment. The idea is if samples are available through the stages of establishing a culture, the cells can be replaced if contaminated or otherwise lost.

Therefore, at the time of filing, it would have been obvious to the ordinary artisan to freeze aliquots or hES cells cultured in human fibroblast conditioned media as taught by Xu using the cryopreservation method of Lim.

Claims 1, 4, 15, 17 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xu et al., Nature Biotech, October 2001, pages 971-974 in view of WO00/029001 published May 25, 2000 (Mc Intosh).

Xu teaches a culture of hES cells grown in media supplemented with conditioned media prepared from TERT immortalized human foreskin fibroblasts (page 971, col. 2, parag. 1, lines 2-11). Xu teaches a method of subculturing by indication of passage 32 (page 972, Figure 1).

Mc Intosh teaches fibroblast cell line 1087sk, ATCC CRL-2104 (page 11, lines 20-22). Mc Intosh further teaches the media from culturing the 1087sk cells was used to prepare conditioned media (page 13, lines 3-7).

Thus, at the time of the instant invention, it would have been obvious to culture hES cells using conditioned media from CCS-1087sk given the teachings of Xu that human adult fibroblasts could produce conditioned media sufficient to maintain pluripotency of hES cells, in view of Mc Intosh teaching CCD-1087sk human adult fibroblasts and the production of conditioned media from them. The artisan would have known at the time of filing to obtain CCD-1087sk cells from the ATCC. The claims require growth on CCD-1087sk feeder cells or growth in conditioned media prepared for CCD-1087sk cells.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is (571)272-0727. The examiner can normally be reached on M-Fri, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deborah Crouch, Ph.D./
Primary Examiner, Art Unit 1632

September 29, 2008